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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TSOY, ELENA

ART UNIT

PAPER NUMBER

1762

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,168

Applicant(s)

LOHMANN ET AL.

Examiner

Elena Tsoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-17) in Paper No. 6 is acknowledged. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.)
or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Claims 4, 7, 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12, line 3, the suffix "able" (obtainable, preparable, derivable, etc.) when recited in conjunction with a process ("coating obtainable by the process...") renders the claim indefinite since it is not possible to determine with certainty when such a claim is infringed, i.e. exactly when a product is "able" to be made by the claimed process and when it is not.

Claim 13 provides for the use of a comb-type polymer, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-3, 11, 12, 14** rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al (US 6,090,995) in view of Meyer et al (US 6,280,760).

Daroux et al (US 6,648,186) is applied herein as evidence.

Reich et al disclose a method for modifying a synthetic surface, such as surface of various implants (See column 2, lines 22-28; column 3, lines 35-40) such as hydrogel lens (See column 4, line 26), the method comprising applying to a synthetic surface a surface modifying composition comprising a polymer having pendant functional groups capable of being converted to nitrene (or other highly reactive) groups (triggerable precursor) and then converting the functional groups to highly reactive groups and thereby covalently binding the surface modifying composition to the synthetic surface (See column 2, lines 15-22) using UV or visible light (See column 4, lines 21-

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36). The surface modifier composition can be based on **virtually any polymer** having a plurality of pendant groups. Preferred polymers include a plurality of pendant amino and/or carboxyl groups and are exemplified by poly(amino acid)s such as poly(lysine) (See column 3, lines 47-55). A portion of the pendant amino groups of a poly(lysine) polymer can be derivatized by reacting the lysine polymer with N-hydroxysuccinimidyl-4-azidobenzoate ("HSAB"), a polyfunctional compound which contains an amine-reactive group as well as an azido group. Upon incubation of a hydrogel lens with the HSAB-derivatized poly(lysine), and photolysis with UV light (typically in the 265-275 nm range), the poly(lysine) chains are covalently bound to the surface of the lens. Crosslinking among polymer chains or with other materials which may be incorporated within the surface modifier composition also occurs (See column 4, lines 21-36). Preferred other materials for incorporation into the surface modifier compositions are biological materials, which are known to support the growth, migration and attachment of epithelial cells, including **virtually any protein** desired to be covalently attached to the synthetic surface. If desired, these materials may be altered, derivatized or crosslinked prior to being combined with the HSAB-modified poly(lysine) (or other surface modifier) and applied to the synthetic surface. Upon photolysis, the included material is crosslinked by some of the nitrene groups attached to the poly(lysine), whereas other nitrene groups attached to the poly(lysine) covalently bind to the surface. See column 4, lines 16-20.

Reich et al fail to teach that: the surface modifying polylysine (polypeptide) polymer with "virtually any protein" are formed into a comb-type structure of claimed formula (1 d) before binding to the surface, wherein side chains comprise at least one triggerable precursors and have molecular weight of 200 or more (Claims 1-3). The Examiner Note: it is well known in the art that protein includes oligopeptide chains.

Meyer et al teach that cell adhesion of implant surface can be increased by covalent bonding peptides, if desired via branched, surface-enlarging molecules and/or molecular anchors (See column 4, lines 60-68) (so-called dendrimers or Tentakels) (See column 5, lines 19-24). The Examiner Note: dendrimer is a general type of branched polymer, comprising a number of polymeric arms radiating from a central core, as evidenced by Daroux et al (See column 4, lines 23-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified a surface in a method of Reich et al by covalent bonding peptides via branched, surface-enlarging molecules and/or molecular anchors of dendrimer (a comb-type) structure with the expectation of providing the surface with the desired increased cell adhesion, as taught by Meyer et al.

As to molecular weight of side chains being 200 or more, clearly length of side chains in a comb-type polymer would depend on intended use of a final product.

It is held that it is not inventive to discover the optimum or workable ranges of result-effective variables by routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimum values of the relevant length of side chains in comb-type polymer of Reich et al in view of Meyer et al (including claimed 200 or more) through routine experimentation in the absence of a showing of criticality.

5. **Claims 4-10, 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al (US 6,090,995) in view of Meyer et al (US 6,280,760), and further in view of Miyasaka et al (US 4,987,032) and WO 9957581.

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Reich et al in view of Meyer et al fail to teach that modifying polymers are derived from compounds having functional groups L_1 capable of being converted to other highly reactive groups such as carbene and having structure of claimed formulae 14 (Claim 15), 13, 3b (Claim 16) or 10a (Claim 17).

Miyasaka et al teach that *either* a precursor of carbene or a precursor of nitrene can be used for bonding molecules to a surface (See column 3, lines 31-40; column 4, lines 40-46). In other words, a precursor of carbene is functionally equivalent to a precursor of nitrene for forming a reactive monolayer on the surface.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a precursor of carbene such as in a method of Reich et al in view of Meyer et al instead of a precursor of nitrene for bonding a comb-type polymer to a surface since Miyasaka et al teach that a precursor of carbene is functionally equivalent to a precursor of nitrene for molecules to a surface.

WO 9957581 teaches that a polymers of claimed formulae 1, 2a-k, 3, 3a, 3b, 4b, 4c, 13 formed by using a compound 14, 10a (See page 3) are suitable for modifying surfaces of biomedical devices including contact lens (See page 1).

It is held that the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polymer of claimed formulae 13, 3b, 10a formed by using a compound 14 in a method of Reich et al in view of Meyer et al Miyasaka et al for modifying surfaces of biomedical devices since WO 9957581 teaches that a polymers of claimed formulae 1, 2a-k, 3, 3a, 3b, 4b, 4c, 13 formed by using a compound 14, 10a are suitable for modifying surfaces of biomedical devices including contact lens.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (703) 605-1171. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (703) 308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elena Tsoy

Elena Tsoy
Examiner
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May 15, 2003